

Serial Number: 09/534,509

Group Art Unit: 1632

**REMARKS**

By the present amendment, claims 1, 13-19, 24, 33, and 46-55 have been canceled. Accordingly, claims 6, 10-12, and 39-42 have been amended to depend on claim 2 instead of claim 1. These amendments have been made without disclaimer or prejudice, in particular as to the filing of a divisional or continuation application for these claims.

Further, claim 20 has been amended to delete the phrase "for the treatment or the prevention of inflammation or inflammatory-related disorder." It is submitted that this amendment is for simplification only and does not affect the scope of this composition claims.

Claims 1-6, 8-12, 20-23, 25-32, and 34-45 are pending in the present application. Claims 1-6, 8-12, 23, 25-32, 34-37, and 39-42 are directed to methods for the treatment of various affections comprising administration of total yeast RNA, and claims 20-22, 38 and 43-45 are directed to a composition comprising total yeast RNA.

As a preliminary, Applicant and Applicant's representative thank the Examiner for the personal interview which was held on June 12, 2003.

To summarize the Office Action, (i) claims 6 and 8-39 and 46-47 are objected to, (ii) claims 14-19 are rejected under 35 U.S.C. 112, second paragraph, as indefinite, (iii) claims 1 and 6-19 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement, and (iv) this Office Action is made final.

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**I. Objections**

In the Office Action, claims 6 and 8-39 are objected on the grounds that the term "A method" should be replaced by "The method" in the introduction of claims 6-39, and that claims 46-47 are duplicate of claims 13 and 15.

Claims 6, 8-12, 21-23, 25-32 and 34-38 have been amended as suggested by the Examiner, while claim 39 already recites "The method." Further, claims 13-19, 24, 33, and 46-47 have been canceled, so that the objections to these claims are moot.

In view of the above, it is submitted that the objections should be withdrawn.

**II. Indefiniteness Rejection**

In the Office Action, claims 14-19 are rejected under 35 U.S.C. 112, second paragraph, as indefinite, on the ground that the disorder specified in each of these claims lacks antecedent basis.

Since claims 14-19 have been canceled, the rejection of these claims is moot.

**III. Lack of Enablement Rejection**

In the Office Action, claims 1, 6, 8-24, 33 and 38-55 under 35 U.S.C. 112, first paragraph, as not enabled. It is alleged in the Office Action that the specification does not describe sufficiently a method for preventing or treating the various inflammatory disorders listed in claim 1 to enable the rejected claims. In addition, with respect to the composition claims 20-22, 38 and 43-45, it is alleged that the composition is not enabled as a "pharmaceutical composition for the treatment or the prevention of inflammation or inflammatory-related disorder" because no such therapeutic use has been enabled.

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**Reconsideration and withdrawal of the rejection is respectfully requested. First, the rejected method claims 1 and 55 have been canceled, and the claims dependent thereon have either been canceled or made dependent directly or indirectly on claim 2, so that the rejection as applied to these claims is moot. Second, regarding composition claims 20-22, 38 and 43-45, as discussed during the personal interview, it is submitted that the Office Action itself acknowledges some therapeutic use of the composition as listed for example on page 4, lines 1-4 of the Office Action. Therefore, the composition as claimed has utility and is accordingly enabled.**

**In view of the above, it is submitted that the rejection should be withdrawn.**

**IV. Finality of the Response**

**This Office Action is indicated to be final, and it is alleged in the Office Action that the amendments made in the previous response have caused the new lack of enablement rejection.**

**Reconsideration and withdrawal of the finality of the Office Action is respectfully requested. It is submitted that the new lack of enablement rejection was not caused by the last amendments to the claims, but that the same rejection could have been made in an earlier Office Action. More specifically, the amendments to claims 1, 20 and 55 in the last response and supplemental responses did not enlarge the scope of the claims as to the types of pathological conditions in which inflammation or inflammatory-related disorders are present. Thus, the present non-enablement rejection of the amended claims could have been made before the last amendments, and indeed, the rejection could have been made for claims as presented originally in the application, i.e., in the first Office Action.**

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As a reminder, in the first Office Action dated June 26, 2001, a rejection of claims 1 and 6-19 under 35 U.S.C. 112, first paragraph, for lack of enablement, had been set forth, but it was limited to the particular grounds that the invention was not sufficiently described for (i) prevention of inflammation, (ii) RNA other than yeast RNA, (iii) chronic inflammation, and (iv) administration routes other than interabdominal injection.

All these rejections were considered overcome and thus withdrawn in the second Office Action dated January 16, 2002, except the first ground (rejection based on the lack of description of preventive therapeutic effect), which was considered overcome and withdrawn in the first Office Action after RCE, dated July 9, 2002.

In that first Office Action after RCE, a new rejection under 35 U.S.C. 112, first paragraph was made for the composition claims, but this was a lack of written description rejection in connection with the manner of describing the purity levels of the composition, not a lack of enablement rejection, and it has also been overcome and withdrawn in this second Office Action.

In summary, the present lack of enablement rejection is not caused by the recent amendments to the claims, and could have been made in at an earlier stage of prosecution. It is submitted that a final Office Action at this stage is detrimental and unfair to Applicant. Accordingly, it is submitted that the finality of the Office Action should be withdrawn.

**V. Conclusion**

In conclusion, the invention as presently claimed is patentable. It is believed that the claims are in allowable condition and a notice to that effect is earnestly requested.

In the event there is, in the Examiner's opinion, any outstanding issue and such issue may be

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resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

In the event this paper is not considered to be timely filed, the Applicants hereby petition for an appropriate extension of the response period. Please charge the fee for such extension and any other fees which may be required to our Deposit Account No. 01-2340.

Respectfully submitted,

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